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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/669,051	09/24/2000	Nicolas F. Franano	55225	2612

21874 7590 07/25/2003

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EXAMINER

SRIVASTAVA, KAILASH C

ART UNIT PAPER NUMBER

1651

DATE MAILED: 07/25/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/669,051

Applicant(s)

FRANANO, NICOLAS F.

Examiner

Dr. Kailash C. Srivastava

Art Unit

1651

RCE

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on July 03, 2003 as Paper Number 17.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 56-60 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 56-60 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 16.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). _____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other:

DETAILED ACTION

1. Request for continued examination (i.e., RCE) under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application on July 03, 2003 as paper number 17 after Notice of Allowance mailed on April 4 2003 as Paper Number 15. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on July 03, 2003 as Paper Number 17 has been entered. Accordingly an RCE has been established and the action on RCE follows.
2. Applicant's Petition to Withdraw from issue after payment of issue fee filed July 03, 2003 as Paper Number 18 in response to Notice of Allowance mailed April 4, 2003 as paper number 15 is acknowledged and entered.
3. Petitions Examiner has granted Applicant's petition cited *supra*. Accordingly, Decision on Petition was mailed July 23, 2003 as paper Number 19.
4. Claims 56-60 are pending.
5. Claims 56-60 are examined on merits.

Information Disclosure Statement

6. Applicant's Supplemental Information Disclosure (i.e., IDS) filed July 03, 2003 as Paper Number 16 is acknowledged and is considered. Applicant, however, should submit a legible copy of the citation "AL", Curci, J.A. et al., Journal of Vascular Surgery, February 1999, Volume 29 (2), Pages 1-3.

Claim Rejections – 35 U.S.C. § 102

7. The following is a quotation of the appropriate paragraphs of 35 U.S.C. § 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

8. Claims 56-60 are rejected under 35 U.S.C. §102(b) as anticipated by Herring (U.S. Patent 5,041, 091) or Dobrin et al. (Surgery, 1988, 104 (3), Pages 568-571) or Anidjar et al (Circulation, 1990, 82(3), Pages 873-981).

Claims recite a method to treat an obstructed biological conduit by administering a composition comprising a single or a mixture of enzymes, wherein said enzyme are one of collagenases or elastases and said enzymes cause proteolysis of microfibrils in the wall of said conduit leading to the enlargement of the diameter of the lumen of said biological conduit. Said biological conduit is selected from an artery or a vein.

Herring teaches a method to treat a jugular vein with an enzyme solution containing collagenase (Column 4, lines 38-53 and Figures 2-5), wherein collagenase is introduced into said vein through inserting a device. It is true that the functional intended use of the teaching is to harvest endothelial cells from a collagenase treated vein,

nevertheless, the teachings of this prior art reference cover all the limitations of Claims 56-60 because lumen diameter of collagenase treated vein (i.e., a biological conduit) appears to have enlarged as a result of digestion (i.e., proteolysis) of the extracellular matrix of said vein by introducing an enzyme. As discussed *supra*, even though Herring does not explicitly teach enlargement of vein lumen resulting from administering collagenase containing composition, the claims are anticipated by the Examiner-cited prior art reference because the functional intended use of a composition does not materially change a composition and is accordingly, not given any patentable weight. In the instant case, the claims are drawn to a method that utilizes the same composition that results in lumen diameter enlargement. Therefore, the reference deems to anticipate the cited claims.

Dobrin et al. teach a method (Abstract, Lines 3-7) to introduce aneurial dilation in dog carotid arteries by treating said biological conduits with elastase or collagenase, wherein degradation of arterial wall elastin takes place. Thus, teachings from Dobrin et al. seem to indicate an enlargement of a biological conduit lumen because the arterial wall is being degraded as a result of enzyme treatment. Therefore, the reference deems to anticipate the cited claims.

Anidjar et al. teach an in-vivo method (Abstract, Lines 1-4) for aortic aneurysm by treating rat abdominal aorta (i.e., a biological conduit) with elastase, wherein aneurial dilations were observed. Since elastin tissue loss resulted in aneurial dilation, teachings from Anidjar et al. seem to teach an enlargement of a biological conduit lumen as a result of enzyme treatment. Therefore, the reference deems to anticipate the cited claims.

Claim Rejections - 35 U.S.C. § 103

9. The following is a quotation of 35 U.S.C. §103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

10. Claims 56-60 are rejected under 35 U.S.C. § 103 (a) as obvious over Herring (U.S. Patent 5,041, 091) in view of Dobrin et al. (Surgery, 1988, 104 (3), Pages 568-571) and Anidjar et al. (Circulation, 1990, 82(3), Pages 873-981).

Claims recite a method to treat an obstructed biological conduit by administering a composition comprising a single or a mixture of enzymes, wherein said enzyme are one of collagenases or elastases and said enzymes cause proteolysis of microfibrils in the wall of said conduit leading to the enlargement of the diameter of the lumen of said biological conduit. Said biological conduit is selected from an artery or a vein.

Teachings from Herring, Dobrin et al. and Anidjar et al. (Circulation, 1990, 82(3), Pages 873-981) have already been discussed *supra*.

An artisan of ordinary skill would be motivated to obtain a dilation (i.e., an enlargement) of a biological conduit lumen, wherein said biological conduit is an artery or a vein by modifying the teachings from Herring (Column 4, lines 38-53 and Figures 2-5) according to the teachings from Dobrin et al. and Anidjar et al., because all the three prior art references teach injecting an enzyme preparation, wherein said enzyme preparation (i.e., a collagenase or an elastase) degrades the wall of the treated conduit and results into enlargement of the lumen of said biological conduit (i.e., artery or vein). Dobrin et al. (Abstract, Lines 3-7) remedy the deficiencies in teachings from Herring because they teach injecting collagenase or elastase in to dog carotid artery to obtain aneurysm and degradation of arterial wall (i.e., enlargement of arterial lumen) and Anidjar et al. (Abstract, Lines 1-4) remedy the deficiencies in teachings of both Herring and Dobrin et al. because Anidjar et al. teach that enlargement of rat aorta lumen following treatment with elastase was observed under in-vivo conditions.

Since each one of the cited prior art references teach a method and a composition comprising ingredients that are common to instantly claimed invention (e.g., a method to enlarge the lumen of an artery or a vein by treating said artery or vein with an enzyme preparation), it would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was made to combine the teachings from each one of the cited references to enlarge the lumen of a biological conduit by removing the obstruction that caused diminution of biological conduit lumen by treating said biological conduit (i.e., an artery or a vein) with an enzyme preparation comprising collagenase or elastase, wherein said preparation was introduced to the biological conduit of interest (i.e., vein or artery) with a syringe or a catheter.

From the teachings of the references cited *supra*, it is apparent that one of ordinary skill in the art would have had a reasonable expectation of success in producing the claimed invention. Therefore, the invention as a whole was *prima facie* obvious to one of ordinary skill in the art at the time the invention was made, as evidenced by the references, especially in the absence of evidence to the contrary.

CONCLUSION

11. No Claims are allowed.

12. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Examiner Kailash C. Srivastava whose telephone number is (703) 605-1196. The examiner can normally be reached on Monday-Thursday from 7:30A.M. to 6:00 P. M. (Eastern Standard or Daylight Saving time).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Wityshyn, can be reached on (703) 308-4743 Monday through Thursday. The fax phone number for the organization where this application or proceeding is assigned is (703) 305-3014.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

Kailash C. Srivastava, Ph.D.
Patent Examiner
Art Unit 1651
(703) 605-1196

July 24, 2003



CHRISTOPHER R. TATE
PRIMARY EXAMINER

Notice of References Cited

Application/Control No.

09/669,051

Applicant(s)/Patent Under
Reexamination
FRANANO, NICOLAS F.

Examiner

Dr. Kailash C. Srivastava

Art Unit

1651

Page 1 of 1

U.S. PATENT DOCUMENTS

*		Document Number Country Code-Number-Kind Code	Date MM-YYYY	Name	Classification
	A	US-5,041,091	08-1991	Herring, Malcolm B.	604/102.03
	B	US-			
	C	US-			
	D	US-			
	E	US-			
	F	US-			
	G	US-			
	H	US-			
	I	US-			
	J	US-			
	K	US-			
	L	US-			
	M	US-			

FOREIGN PATENT DOCUMENTS

*		Document Number Country Code-Number-Kind Code	Date MM-YYYY	Country	Name	Classification
	N					
	O					
	P					
	Q					
	R					
	S					
	T					

NON-PATENT DOCUMENTS

*		Include as applicable: Author, Title Date, Publisher, Edition or Volume, Pertinent Pages)
	U	
	V	
	W	
	X	

*A copy of this reference is not being furnished with this Office action. (See MPEP § 707.05(a).)
Dates in MM-YYYY format are publication dates. Classifications may be US or foreign.